12/9/97

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office
700

297 Plus Park Blvd.
Nashville, TN 37217

November 26, 1997

11/28/97
YES

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER-98-NSV-05

FACILITY ID# 211391

Jim Ailshie, Clinical Administrator
John Deere Family Healthplan
2578 East Stone Drive, Suite B
Kingsport, TN 37660

Dear Mr. Ailshie:

Your facility was inspected on November 12, 1997 by a representative of the State of Tennessee, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The calculated mean glandular dose exceeded [redacted] mrads (measured dose = [redacted] mrad): [redacted]. **OTHER; Mammography.**

This specific deficiency appears on the List of Observations which was given to your facility at the close of your inspection. This deficiency is symptomatic of a serious problem that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

We received a letter dated November 19, 1997 from Melissa Burton, R.T., and this letter indicated that your facility was meeting with service company representatives to resolve the problem in an expeditious manner.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency that the inspection identifies and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Consumer Safety Officer, at 615/781-5380, extension 144.

Sincerely,

Raymond K. Hedblad

Raymond K. Hedblad
Director, Nashville District

RKH/ks

cc: State of Tennessee
Darlene Nalepa-Whitmill, Dept. of Env. and Consv., 2700 Middlebrook Pike, Suite 200
Knoxville, TN 37921